Routine stenting improved outcomes and had similar costs to that of balloon angioplasty with provisional stenting

Weaver WD, Reisman MA, Griffin JJ, et al., for the OPUS-1 Investigators. **Optimum percutaneous transluminal coronary angioplasty compared with routine stent strategy trial (OPUS-1): a randomised trial.** Lancet. 2000 Jun 24;355:2199-203.

QUESTION

How does routine stenting compare with balloon angioplasty with provisional stenting in patients with coronary stenosis?

DESIGN

Randomized (allocation concealed*), unblinded,* controlled trial with 6-month follow-up.

SETTING

44 hospitals in the United States and Canada.

PATIENTS

479 patients between 21 and 81 years of age (median age 60 y, 73% men) who had stable or unstable angina or a positive functional test for ischemia or who were having angioplasty after a recent myocardial infarction (MI) (> 24 h). Inclusion criteria included having ≥ 70% stenosis in native coronary arteries, a single lesion of ≤ 20 mm in length, a coronary artery reference diameter ≥ 3.0 mm, and an eligible target-vessel lesion that was treatable by balloon angioplasty or a stent. Exclusion criteria included complex lesions. Follow-up was 99.5%.

INTERVENTION

Patients were allocated to routine stent implantation (n = 230) or optimal balloon angioplasty with provisional stenting if an optimal result could not be achieved (n = 249).

MAIN OUTCOME MEASURE

The primary end point was the composite rate of death, MI, cardiac surgery, or target-vessel revascularization.

MAIN RESULTS

Analysis was by intention to treat. 227 patients (99%) in the routine-stent group and 93 patients (37%) in the group having balloon angioplasty with provisional stenting had ≥ 1 stent implantation. Routine stenting reduced the composite end point of death, MI, cardiac surgery, or target-vessel revascularization ($P < 0.01$); target-vessel revascularization ($P < 0.05$); and revascularization or surgery ($P < 0.01$) more than did balloon angioplasty with provisional stenting (Table). The mean per-patient hospital costs (U.S. $10 206 vs $10 490) and quality of life did not differ.

CONCLUSION

Routine stent implantation improved clinical outcomes and had a cost similar to that of balloon angioplasty with provisional stent implantation in patients with coronary stenosis.

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For correspondence: Dr. W.D. Weaver, Division of Cardiovascular Medicine, Henry Ford Health System, Heart and Vascular Institute, 2799 West Grand Boulevard, Detroit, MI 48202, USA. FAX 313-916-1249. ■

*See Glossary.

Routine stenting vs optimal balloon angioplasty with provisional stenting in coronary stenosis†

Outcomes at 6 mo	Routine stent	Provisional stent	RRR (95% CI)	NNT (CI)
Composite end point‡	6.1%	14.9%	59% (27 to 77)	11 (7 to 30)
Target-vessel revascularization	3.9%	10.1%	61% (20 to 81)	16 (9 to 62)
Revascularization or surgery	5.2%	12.9%	59% (24 to 78)	13 (8 to 39)

†Other abbreviations defined in Glossary; RRR, NNT, and CI calculated from data in article.
‡Death, myocardial infarction, cardiac surgery, or target-vessel revascularization.

COMMENTARY

Although > 50% of all percutaneous coronary interventions involve stenting (> 300 000 patients/y in North America), few studies have addressed this key issue. The OPUS-1 investigators make an important contribution by comparing provisional stenting with routine stenting with balloon angioplasty when the residual stenosis was > 30% or when dissection or threatened closure occurred.

Several limitations of the study highlight the paucity of evidence to support routine stenting, which is becoming routine practice. First, the primary end point occurred in only 51 patients and was driven by the need for target-vessel revascularization using a repeated percutaneous intervention, an outcome measure that may be influenced by perceptions in an unblinded study (1). Second, the anticipated 25% event rate and 20% relative risk reduction (RRR) with routine stenting required a sample size 5 times greater than that obtained. The fact that a significant difference was achieved with an event rate of only 15% relates to the dramatic 59% RRR with routine stenting. Third, despite the decrease in revascularization, patient-reported quality of life, functional status, and cost at 6 months were similar in the 2 groups. Fourth, it may be difficult to interpret the results of this study, where only 13% of the patients received abciximab. In current-day practice, strong data support routine use of glycoprotein IIb/IIIa inhibition during percutaneous intervention. Although more data are desirable to increase confidence in the benefits of routine stenting, such confidence will not be obtained from OPUS-1 because it was discontinued after a low recruitment rate and lack of funding. At present, it seems reasonable to conclude that routine stenting improves clinical outcomes at a 6-month cost similar to that of balloon angioplasty with provisional stenting.

Shaun Goodman, MD, MSc
St. Michael's Hospital
Toronto, Ontario, Canada

Reference

1. **Stables RH.** Strategies for coronary stenting. Lancet. 2000;355:2180-1.

